IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF WYOMING

WYOMING PREMIUM FARMS, LLC, a Wyoming Limited Liability Company, Plaintiff, v. PFIZER, INC., a Delaware Corporation, and WYETH HOLDINGS CORPORATION, a Maine Corporation, Defendants.	)	No. 11-CV-282-J

OPINION AND ORDER GRANTING MOTION FOR JUDGMENT ON THE PLEADINGS

The defendants' Motion for Judgment on the Pleadings (Docket Entry 21), the plaintiffs' response in opposition to the motion (Docket Entry 27), and the defendants' further reply (Docket Entry 28) have come before the Court for consideration. The Court has considered the parties' submissions, all pleadings of record, the applicable law and FINDS and ORDERS that the defendants' motion should be granted and that judgment should be entered accordingly in favor of the defendants.

Review of the motion is informed by Bixler v. Foster, 596 F.3d 571, 755

(n.2)-756 (10th Cir. 2010), in which the appellate court stated:

> Our standard of review for rulings under Rule 12(b)(6) and Rule 12(c) is the same—de novo. Corder v. Lewis Palmer Sch. Dist. No. 38, 566 F.3d 1219, 1223 (10th Cir. 2009), cert. denied, --- U.S. ----, 130 S.Ct. 742, 175 L.Ed.2d 515 (2009).
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> * * * *
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> We review de novo the district court's Rule 12(b)(6) dismissal. See Christy Sports, LLC v. Deer Valley Resort Co., 555 F.3d 1188, 1191 (10th Cir. 2009). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" Ashcroft v. Iqbal, --- U.S. ----, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). "[W]e assume the factual allegations are true and ask whether it is plausible that the plaintiff is entitled to relief." Gallagher v. Shelton, 587 F.3d 1063, 1068 (10th Cir. 2009). "[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Iqbal, 129 S.Ct. at 1949.

The plaintiff's (hereafter plaintiff is referred to most often as "WPF") complaint in this action arises out of the purchase and sale of a vaccine for circovirus in pigs known as Suvaxyn. WPF's manager contacted a representative of Fort Dodge Animal Health, which is a division of defendant Wyeth. The complaint alleges that the defendants' representative recommended the Suvaxyn vaccine, and based on the representative's recommendation and WPF's review of advertisements and literature of Fort Dodge Animal Health, the

decision was made to purchase that vaccine. Complaint ¶ 13. Fort Dodge required that WPF purchase the vaccine through its own veterinarian, Anthony Scheiber. Complaint ¶ 14. Through him, between January and July of 2007, WPF purchased 493 bottles of Suvaxyn circovirus vaccine (123,500 doses) for $184,875.00. Complaint ¶ 15. WPF began vaccinating its pigs and by late summer and early fall of 2007, determined the pig mortality rate was not decreasing. Complaint ¶ 17. WPF then told Fort Dodge Animal Health of its concerns, and Fort Dodge's representatives requested tissue samples from pigs that had died after vaccination to be used in lab testing, which WPF provided. WPF alleges that it was told there was no live virus in the vaccine, but was never told if the samples had been tested for circovirus and, if testing had been done, it was not told of the findings. Complaint ¶ 18.

Suvaxyn was to be manufactured using killed virus. WPF asserts that the vaccine "may contain live virus and that instead of controlling the virus, the administration of the vaccine may instead be introducing it. To assure that the vaccine contained no live virus, in October, 2007, WPF's veterinarian Anthony Scheiber, at the direction of WPF, sent samples of the vaccine to the Veterinary Diagnostic laboratory at Iowa State University. The results showed that the vaccine contained no live virus." Complaint ¶ 19. Thereafter WPF continued

to vaccinate pigs with the Suvaxyn vaccine through mid-February 2008. The pig mortality rate continued to be abnormally high, so WPF's veterinarian began to search for and found another circovirus vaccine from a different pharmaceutical company. By May of 2008, WPF asserts the new vaccine had successfully controlled the circovirus and mortality rates returned to normal. Complaint ¶¶ 20, 21.

In January of 2008, WPF's veterinarian sent tissue samples from a 13 week old pig vaccinated with Suvaxyn to a laboratory in South Dakota for testing. Analysis revealed the presence of circovirus. Autopsies on other pigs also showed the presence of circovirus. WPF alleges that the lab results and autopsies, along with the successful results from the use of the other vaccine, showed "that the Fort Dodge Animal Health Suvaxyn circovirus vaccine was not effective and had not controlled circovirus in WPF's pigs." Complaint ¶ 22. WPF now seeks to recover for its financial losses.

In the complaint several causes of action are asserted:

(1) Breach of Express Warranty. Complaint ¶¶ 24-28.

(2) Breach of Implied Warranties of Merchantability and Fitness for a Particular Purpose. Complaint ¶¶ 29-38.

(3) Strict Products Liability -- § 402A, Restatement (Second) of Torts.

Complaint ¶¶ 39-44.

(4) Misrepresentation -- § 402B, Restatement (Second) of Torts). Complaint ¶¶ 43-49.

(5) Negligence. Complaint ¶ 50-54.

The defendants' motion seeks judgment on the pleadings pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. They argue that the state law claims asserted by WPF in its complaint are preempted by federal law. They assert that the WPF claims are barred by conflict preemption because imposing additional or different state law requirements on the efficacy of veterinary biologics obstructs the congressional objective of implementing uniform standards of efficacy. Defendants argue that the WPF claims are also barred by the impossibility conflict preemption doctrine because defendants could not simultaneously comply with applicable federal law and the state tort duties plaintiff has asserted. Finally, defendants contend that field preemption bars WPF's claims because Congress has occupied the field of veterinary biologics licensure.

Plaintiff opposes the motion, disputing that its claims are preempted by the "purposes and objectives" conflict and impossibility conflict doctrines and that there is no evidence of congressional intent to preempt state law. WPF

asserts that defendants are unable to show compliance with the applicable federal regulations cannot be accomplished concurrently with Wyoming tort and contract law. WPF further argues that Congress has shown no intent to occupy the field with respect to animal vaccines.

Discussion

The Court finds that all of the plaintiff's state law claims are preempted by federal law and that judgment should be entered in favor of defendants. This determination is made following a review of the regulatory scheme governing animal vaccines.

Suvaxyn, the porcine circovirus vaccine at issue in this case, was licensed by the United States Department of Agriculture ("USDA") and the Animal and Plant Health Inspection Services agency ("APHIS") of the USDA. Animal biologic products, which include vaccines, are regulated through the Virus-Serum-Toxin Act ("VSTA"), 21 U.S.C. §§ 151-159. VSTA authorizes the USDA to license and regulate the preparation and sale of "viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals." 21 U.S.C. § 154. The 1985 amendment of VSTA clearly placed both interstate and intrastate vaccines within the ambit of federal control. 21 U.S.C. § 151; S.Rep. No. 145, 99th

Cong., 1st Sess. 338-39-1985, reprinted in 1985 U.S.C.C.A.N. 1676, 2004-05. "The need for uniform national standards has become recognized widely in recent years." S. Rep. No. 145, 99th Cong., 1st Sess. 338-39 (1985, reprinted in 1985 U.S.C.C.A.N. 1676, 2005). "The amendments reflect the Congressional finding that federal regulation was 'necessary to prevent and eliminate burdens on commerce and to effectively regulate such commerce.' 21 U.S.C. § 159." Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d 620, 625 (7th Cir.), reh. and suggestion for reh. denied (1996), cert. denied, 519 U.S. 867 (1996).

APHIS is the agency in the USDA responsible for administering VSTA. 9 C.F.R. § 101.2. APHIS has "promulgated an extensive regulatory scheme governing the design, manufacture, distribution, testing, and labeling of animal vaccines." Symens v. SmithKline Beecham Corp., 152 F.3d 1050, 1052 (8th Cir. 1998), quoting Lynnbrook Farms v. SmithKline Beecham Corp., 79 F.3d at 624, and citing 9 C.F.R. §§ 101-124.[1] Under this regulatory scheme, 9 C.F.R. §

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[1]There is no claim here that the rule-making process employed to craft this regulatory scheme is infirm. Comments were solicited by APHIS, and were responded to in promulgating the final rule. At 57 Fed. Reg. 38759, the agency states: "The regulation will not be amended based on these comments because the purpose of the Act is to assure that biologics used in the treatment of animals are pure, safe, potent, and efficacious. The public benefits as a result of the successful protection of animals from various diseases, including those which are of great public concern such as rabies. Since safe and effective (continued...)

102.4, provides in part:

> (b) A license shall not be issued unless:
>
> (1) In the opinion of the Administrator, the condition of the establishment, including its facilities, and the methods of preparation of biological products are such as reasonably to assure that the products shall accomplish the purpose for which they are intended; and
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> (2) The Administrator is satisfied on the basis of information before him that:
>
> > (I) The establishment shall be operated in compliance with the Act and applicable regulations and be under the supervision of person(s) competent in the preparation of biological products; and
> >
> > (ii) The applicant, or the person having the responsibility for producing biological products in the establishment, or both, is qualified by education and experience, and has demonstrated fitness to produce such products in compliance with the Act and regulations issued pursuant thereto; Provided, That, previous violations of the Act, or such regulations or both shall be relevant to the Administrator's

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[1](...continued)
vaccines and other biologics are in the public interest, APHIS has used this term in the regulations." There is nothing that is offered by anyone in this case that suggests the agency's position that VSTA preempts state law was not consistent with its previous position. APHIS has consistently maintained that state common law causes of action pertaining to safety, potency, purity or efficacy of veterinary biologics are preempted. This supports the notion that deference should be given to the agency's assertion that state law is preempted.

determination of fitness.

> (3) Written assurance is filed with Animal and Plant Health Inspection Service that the biological products which are licensed to be prepared therein shall not be so advertised as to mislead or deceive the purchasers and that the packages or containers in which the same are to be marketed shall not bear any statement, design, or device which is false or misleading in any particular.

The APHIS regulatory scheme for animal vaccines is comprehensive. A few provisions are here highlighted, but these of course are not exhaustive. When evaluating biological products certain testing terminology is employed. For instance:

> (a) Standard Requirement. Test methods, procedures, and criteria established by Animal and Plant Health Inspection Service for evaluating biological products to be pure, safe, potent, and efficacious, and not to be worthless, contaminated, dangerous, or harmful under the Act.

9 C.F.R. § 101.5(a).

Information that must be included in applications for an animal vaccine license is identified in 9 C.F.R. § 102.3, which requires, among other things, an Outline of Production prepared in accordance with §§ 114.8 and 114.9, and copies of test reports and research data "sufficient to establish purity, safety, potency, and efficacy of the product." 9 C.F.R. § 102.3(b)(2)(ii). Labels, packaging information and advertising matter must also be provided and

approved by APHIS. No license may issue unless:

> (1) In the opinion of the Administrator, the condition of the establishment, including its facilities, and the methods of preparation of biological products are such as reasonably to assure that the products shall accomplish the purpose for which they are intended; and
>
> (2) The Administrator is satisfied on the basis of information before him that:
>
> > (I) The establishment shall be operated in compliance with the Act and applicable regulations and be under the supervision of person(s) competent in the preparation of biological products; and
> >
> > (ii) The applicant, or the person having the responsibility for producing biological products in the establishment, or both, is qualified by education and experience, and has demonstrated fitness to produce such products in compliance with the Act and regulations issued pursuant thereto; Provided, That, previous violations of the Act, or such regulations or both shall be relevant to the Administrator's determination of fitness.
>
> (3) Written assurance is filed with Animal and Plant Health Inspection Service that the biological products which are licensed to be prepared therein shall not be so advertised as to mislead or deceive the purchasers and that the packages or containers in which the same are to be marketed shall not bear any statement, design, or device which is false or misleading in any particular.

9 C.F.R. § 102.4(b).

Once a license has been issued, preparations of licensed biological

products cannot be changed without APHIS approval. 9 C.F.R. § 102.5. The regulations include provisions for sampling and testing protocols, see e.g., 9 C.F.R. § 113.3-113.10. "A biological product shall with reasonable certainty yield the results intended when used as recommended or suggested in its labeling or proposed labeling prior to the expiration date." 9 C.F.R. § 113.6. APHIS may cause biological products manufactured in the United States to be examined and tested for purity, safety, potency or efficacy, and the licensee must withhold the product from the market until a determination has been made. 9 C.F.R. § 113.6(a). The regulations even provide:

> § 114.15 Disposal of unsatisfactory products and byproducts.
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> All biological products found to be unsatisfactory for marketing, all biological products which have become worthless subsequent to the expiration date, all refuse, other materials deemed unsatisfactory for production purposes, all carcasses (part or whole) of production or test animals, and any undesirable byproducts of manufacture shall be disposed of as may be required by the Administrator.

9 C.F.R. § 114.15. Inspections of facilities where biologic products are manufactured are permitted by regulation at any time, day or night, to determine whether such products are worthless, contaminated, dangerous or harmful. 9 C.F.R. Part 115.

Against this regulatory backdrop, the defendants in this case argue that

the plaintiff's state law claims are preempted by federal law. The preemption analysis begins with Article VI, cl. 2 of the United States Constitution:

> Clause 2. Supreme Law of Land
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> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

In Kurns v. Railroad Friction Products Corp., 132 S.Ct. 1261, 1265-1266 (2012), the most recent opinion addressing preemption, the United States Supreme Court stated:

> Pre-emption of state law thus occurs through the "direct operation of the Supremacy Clause." Brown v. Hotel Employees, 468 U.S. 491, 501, 104 S.Ct. 3179, 82 L.Ed.2d 373 (1984). Congress may, of course, expressly pre-empt state law, but "[e]ven without an express provision for preemption, we have found that state law must yield to a congressional Act in at least two circumstances." Crosby v. National Foreign Trade Council, 530 U.S. 363, 372, 120 S.Ct. 2288, 147 L.Ed.2d 352 (2000). First, "state law is naturally preempted to the extent of any conflict with a federal statute." Ibid. Second, we have deemed state law pre-empted "when the scope of a [federal] statute indicates that Congress intended federal law to occupy a field exclusively." Freightliner Corp. v. Myrick, 514 U.S. 280, 287, 115 S.Ct. 1483, 131 L.Ed.2d 385 (1995).

"The phrase 'Laws of the United States' encompasses both federal statutes themselves and federal regulations that are properly adopted in

accordance with statutory authorization." City of New York v. F.C.C., 486 U.S. 57, 63, 108 S.Ct. 1637, 1642 (1988). Further, "'a federal agency acting within the scope of its congressionally delegated authority may pre-empt state regulation' and hence render unenforceable state or local laws that are otherwise not inconsistent with federal law." Id., 486 U.S. at 64. The Supreme Court continued in City of New York:

> . . . . here the inquiry becomes whether the federal agency has properly exercised its own delegated authority rather than simply whether Congress has properly exercised the legislative power. Thus we have emphasized that in a situation where state law is claimed to be pre-empted by federal regulation, a "narrow focus on Congress' intent to supersede state law [is] misdirected," for "[a] pre-emptive regulation's force does not depend on express congressional authorization to displace state law." Fidelity Federal Savings & Loan Assn. v. De la Cuesta, 458 U.S. 141, 154, 102 S.Ct. 3014, 3023, 73 L.Ed.2d 664 (1982). Instead, the correct focus is on the federal agency that seeks to displace state law and on the proper bounds of its lawful authority to undertake such action. The statutorily authorized regulations of an agency will pre-empt any state or local law that conflicts with such regulations or frustrates the purposes thereof. Beyond that, however, in proper circumstances the agency may determine that its authority is exclusive and pre-empts any state efforts to regulate in the forbidden area. Crisp, 467 U.S., at 700, 104 S.Ct. at 2700; De la Cuesta, supra, 458 U.S., at 152-154, 102 S.Ct., at 3022-3023. It has long been recognized that many of the responsibilities conferred on federal agencies involve a broad grant of authority to reconcile conflicting policies. Where this is true, the Court has cautioned that even in the area of pre-emption, if the agency's choice to pre-empt "represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the

> statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned." United States v. Shimer, 367 U.S. 374, 383, 81 S.Ct. 1554, 1560, 6 L.Ed.2d 908 (1961); see also Crisp, supra, 467 U.S., at 700, 104 S.Ct., at 2700.

Id., 486 U.S. at 64-65.

As the Supreme Court stated, a narrow focus on the congressional intent to preempt state law is misplaced. Even so, there is quite a bit of legislative history to rely upon, permitting courts to conclude that the congressional intention was to preempt state law with the enactment of VSTA and the concomitant regulatory scheme through which APHIS implements VSTA. In 1913, in the Department of Agriculture Appropriation Act of 1914, Act March 1913, ch 145, Stat. 832, under the heading "Bureau of Animal Industry," Congress enacted federal legislation concerning viruses, serums, toxins, and analogous products. In 1985, PL 99-198, December 23, 1985, 1985 HR 2100, Section 1768 (cited as the "Food Security Act of 1985") did the same, by amending the 1913 "Act entitled "An Act making appropriations for the Department of Agriculture for the fiscal year ending June thirtieth, nineteen hundred and fourteen", approved March 4, 1913 (21 U.S.C. 151)." Id. As discussed in PL 99-198, S. Rep. 99-145, 1985 HR 2100, Sec. 1768, the 1985 amendments provide for interstate and intrastate regulation of viruses, serums,

toxins and analogous products. It recognized the need for uniform national standards. PL 99-198, S. Rep. 99-145

These legislative expressions "evince[] an unquestionable congressional intent to create national, uniform standards for the preparation and sale of animal vaccines." Lynnbrook, 79 F.3d at 625. The Lynnbrook opinion continues by discussing the agency's position regarding VSTA and preemption:

> In reaction to the VSTA amendments, APHIS issued the declaration of preemption relied upon by SBC. The declaration states in relevant part:
>
> > [W]here safety, efficacy, purity, and potency of biological products are concerned, it is the agency's intent to occupy the field. This includes, but is not limited to the regulation of labeling. Under VSTA, Congress clearly intended that there be national uniformity in the regulation of these products.
> > * * *
> > APHIS ... does not agree that States should be allowed to add various restrictions ... based upon a need to protect domestic animals or the public health, interests or safety. Any restrictions, other than those which are necessary to address a local disease condition, should be Federally imposed so that they are uniform nationwide.
> > * * *
> > States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States. Such

> additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp USDA's authority to determine which biologics are pure, safe, potent and efficacious.

57 Fed.Reg. 38758, 38759 (August 27, 1992) (emphasis added).

We find that APHIS acted rationally and within the scope of the authority granted to it by Congress in issuing the above statement seeking to preempt state law. Congress granted the USDA and APHIS the broad regulatory power to promulgate and enforce "such rules and regulations as may be necessary" to prevent the production and sale of any "worthless, contaminated, dangerous or harmful" animal vaccines. Congress also delegated to the USDA and APHIS the responsibility to eliminate "undue burdens" on commerce in this area, and toward that end, to establish a national, uniform regulatory scheme. It is apparent that APHIS' congressional mandate is to ensure safe and effective vaccines while at the same time minimize undue burdens on interstate commerce that often accompany varied state regulation. Given these powers and responsibilities, APHIS was acting rationally, and well within its congressionally delegated discretion, in creating a complex statutory scheme governing the safety, efficacy, purity, and potency of animal vaccines and in pronouncing this scheme to be the exclusive law in the area. The Supreme Court has held that:

> if the agency's choice to preempt "represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned."

City of New York, 486 U.S. at 64, 108 S.Ct. at 1642 (quoting

> United States v. Shimer, 367 U.S. 374, 383, 81 S.Ct. 1554, 1560-61, 6 L.Ed.2d 908 (1961)); de la Cuesta, 458 U.S. at 154, 102 S.Ct. at 3023. The instant case of preemption reflects a prime example of such an accommodation. Nothing in the legislative history of either VSTA or its amendments indicates that APHIS' actions would not be congressionally sanctioned. On the contrary, the course chosen serves only to further VSTA's purposes-further indicating that the agency was acting within its authority and not acting arbitrarily. See de la Cuesta, 458 U.S. at 159, 102 S.Ct. at 3025. Thus we decline to disturb the agency's judgment to preempt state law.

Id. at 625-626.

The Lynnbrook court also considered a 1995 letter by the Acting Administrator of APHIS regarding the agency's position on preemption of state law.[2] The letter indicated that the intent of the agency "in promulgating the

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[2]In In re Universal Service Fund Telephone Billing Practice Litigation, 619 F.3d 1188 (10th Cir. 2010), the appellate court stated that an agency's conclusion that state law is preempted is not necessarily entitled to deference, citing Wyeth v. Levine, 555 U.S. 555, 129 S.Ct. 1187, 1201 (2009). Wyeth did recognize that agencies do have a "unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Id. Universal Service Fund, stated that the "Wyeth decision made clear '[t]he weight we accord the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency and persuasiveness." 619 F.3d at 1200, quoting Wyeth, 129 S.Ct. at 1201. The regulatory scheme here is comprehensive and thorough, has been consistent over an extensive period of time, and may be considered persuasive. There is no indication that the agency's position regarding preemption of state law in the area of veterinary biological products has ever been otherwise.

rule was, and continues to be, to preempt States from imposing other requirements either through statutes, regulations, or other means that are different from, or in addition to those imposed by USDA regarding the safety, efficacy, potency, or purity of a product." Id. at 625. The letter further stated the agency "did not intend to preempt common law actions for damages arising from noncompliance with USDA regulatory standards." Id. The Lynnbrook court continued:

> We must agree with SBC that the correspondence confirms the interpretation that APHIS intended certain state tort claims to be preempted. Contrary to Lynnbrook's argument that APHIS only intended to preempt positive enactments, the agency included in its preemptive scope additional requirements dictated by States via "regulations, statutes, or other means." The phrase "or other means" clearly encompasses state tort claims. Moreover, APHIS' letter signals that state tort claims are available when APHIS regulatory standards are violated or disregarded. The natural conclusion to draw from this statement is that when APHIS regulations are heeded, state tort claims involving the safety, efficacy, potency, or purity of an animal vaccine do not survive. This dichotomy follows from the preemption language chosen by APHIS, as it is precisely when APHIS regulations have been satisfied that a common law action imposes requirements in addition to, or different from, those mandated by APHIS. [FN8 omitted] Where noncompliance is involved, a common law action could simply serve to impose the standards of APHIS. Thus, it is evident that APHIS intended to preempt common law claims relating to areas under its regulatory control (namely the safety, purity, potency, and efficacy of vaccines) which would impose additional or different requirements on vaccines, i.e., common law claims involving regulated areas in cases where the manufacturer

has complied with all APHIS regulations and standards.

Id. at 629-630. Where the claims relate to safety, purity, potency and efficacy, seeking to impose additional or different requirements in these areas, the Lynnbrook court concluded they are preempted. Id. This preemption analysis encompassed claims for strict products liability, breach of implied warranties of fitness for a particular purpose and of merchantability, fraudulent misrepresentation and false advertising under Illinois law, where APHIS had already declared the products safe and efficacious. Id.

In Symens v. SmithKline Beecham Corp., 152 F.3d 1050, 1055 (8th Cir. 1998), the Eighth Circuit's analysis was similar. It stated that "common law claims are *not* preempted *to the extent that* they seek relief for alleged violations of the federal substantive standards," generally discussed in the case law as claims asserting non-compliance with the federal regulatory standards. This case also cited and relied upon the letter from the APHIS Acting Administrator in reaching its conclusion.

Plaintiff WPF has relied on Behrens v. United Vaccines, Inc., 189 F. Supp.2d 945 (D.Minn. 2002), to challenge the argument that its state law claims are preempted by federal law. In that case owners of a mink ranch brought suit against the manufacturer of an ineffective canine distemper

vaccine that had been given to their minks. That court found their strict liability, negligence and breach of implied warranty claims against the manufacturer of the vaccine were preempted. However, the Behrens court considered the plaintiffs' express warranty claims, alleging that the manufacturer's representative had stated the vaccine was 95 percent effective. The Behrens court found the express warranty claim was not preempted by VSTA. This, WPF contends, at least permits a finding that some state common law claims are not preempted. The promotional statement made by the defendant in Behrens that the vaccine was 95 percent effective was, in that court's view, distinguishable from the representations in Cooper, discussed below, in that its representations were express and beyond what was required by federal law:

> Here, the Defendant's promotional statement, that its product would be "95 per cent effective," was not required by any APHIS labeling requirement, at least as disclosed in this Record, and we are unable to conclude, as the Court did in Cooper, that the representation was "not 'substantially different'" from the statements "set forth in the APHIS-approved labeling and packaging that accompanied Biocom-DP." Cooper v. United Vaccines, Inc., supra at 872. [FN14 omitted] To assure consumers, that a product is effective in preventing distemper—to the extent of a finite, quantified percentage—is starkly different from assuring that the product "aids in the prevention of," or "produces a significant effect."

Behrens, 189 F. Supp.2d at 965 (footnote omitted).

The Cooper case, 117 F. Supp.2d 864 (E.D. Wis.2000), cited in Behrens, also involving mink vaccinations produced by the same company as in Behrens, found the breach of express warranty claim was preempted. The representations made by the company's representatives regarding effectiveness of the vaccine concerned the efficacy of the vaccine. The representations did not include any representations similar to those in Behrens, such as 95 percent effective. For Cooper to have prevailed at trial, the jury would have had to find the vaccine ineffective. "'However, APHIS has already declared the products safe and effective [through the approval process].'" Cooper, 117 F. Supp.2d at 872, quoting Lynnbrook Farms, 79 F.3d at 630. The express warranty claim was preempted.

The representations alleged in WPF's complaint do not meaningfully differ from those in the Cooper case and clearly implicate the efficacy of the Suvaxyn circovirus vaccine. APHIS has already declared the vaccine safe and effective through the approval process. A "different standard would be enforced if [WPF] prevailed on [its] express warranty claim." Id., 117 F. Supp.2d at 872. The Court finds that the express warranty claim is preempted by federal law.

As to the remainder of the plaintiff's claims, for all the reasons discussed

above, the Court finds that they are also preempted by federal law. This includes strict liability, breach of implied warranties of merchantability and fitness for a particular purpose, misrepresentation (§ 402B), and negligence claims. Such claims would pose material impediments or thwart federal policy designed to achieve uniform national standards in the area of animal biological products, such as the Suvaxyn circovirus vaccine. These state law claims conflict with federal law in this preempted field.

The Court recognizes that, as did Lynnbrook court, that the conclusion reached in this Order and Opinion leaves WPF with no remedy for the injuries and losses they claim to have suffered. However, this Court is "not at liberty to reverse the judgments of an agency acting within its congressionally delegated authority. It is evident not only that APHIS intended claims such as those brought by [WPF] to be preempted, but also that Congress granted APHIS the power to act on those intentions." Lynnbrook, 79 F.3d at 630.

It is opportune to once again consider this matter in light of the United States Supreme Court's 2012 discussions in Kurns. Here it is not difficult to conclude that all of the state law claims asserted by WPF concern the efficacy of the Suvaxyn circovirus vaccine and are preempted to the extent they conflict with federal law. Further, upon review of the federal law, including the

agency's regulatory scheme, it is not difficult to conclude that Congress has intended federal law to occupy the field exclusively. Allowing WPF's state law claims to proceed would interfere with APHIS's authority to determine whether the vaccine at issue is pure, safe, potent and efficacious, and not worthless, contaminated, dangerous, or harmful. The plaintiff's argument that VSTA does not contain an express preemption provision reflecting congressional intent is not persuasive, particularly in light of Kurns. Congressional intent is clear that pursuant to VSTA, all matters concerning the safety, purity, potency, and efficacy of animal vaccines have been assigned to the USDA, with authority to promulgate regulations being properly designated to APHIS, for the purpose of achieving uniform national standards of safety, purity, potency and efficacy for veterinary biological products. The efficacy of the Suvaxyn circovirus vaccine had already been declared safe and effective through the APHIS approval process. The state law claims asserted by plaintiff here all concern the efficacy of the Suvaxyn circovirus vaccine. The Court now finds and concludes that these state law claims are all preempted by federal law.

Therefore, accepting all allegations in plaintiff's complaint as true, the Court finds and concludes that all state law claims asserted by WPF are preempted by federal law and that the defendants' motion for judgment on the

pleadings should be granted. Accordingly, it is therefore

ORDERED that defendants' motion for judgment on the pleadings shall be, and is, **GRANTED.**

Judgment shall be entered accordingly.

Dated this 26th day of August 2013.

ALAN B. JOHNSON
UNITED STATES DISTRICT JUDGE